K112977

MAR 27 2012

6. 510(K) SUMMARY

510(k) Summary

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

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Date Summary Prepared: February 24, 2012

Device Subject to this 510(k):

Trade Name:	Monarch® III IOL Delivery System (C Cartridge)
Common Name:	Intraocular Lens Guide
Classification Name:	21 CFR 886.4300

1. Predicate Devices:

The legally marketed device(s) to which we are claiming substantial equivalence are:

510(k) Number	Device
K001157	Monarch® II (C Cartridge) IOL Delivery System
K063155	Monarch III (D Cartridge) IOL Delivery System

2. Device Description:

The Monarch® III IOL Delivery System (C Cartridge), hereafter referred to as the Monarch® III C Cartridge, is a modification to the previously cleared Alcon Monarch® II IOL Delivery System (C Cartridge) consisting of a disposable polypropylene cartridge and reusable titanium handpiece. The Monarch® III C Cartridge features nozzle tip sizing like the currently marketed Monarch® II C Cartridge and is intended to fold and deliver Alcon AcrySof® intraocular lenses into the posterior chamber of the eye. The width of the loading zone has

been increased to ease loading of 6 mm lenses. The exterior body has been modified, similar to Monarch® III D cartridge to improve manufacturability. It is designed to work with the currently marketed Monarch® III handpiece, and has been qualified for use with Alcon's AcrySof® Intraocular Lens models.

3. Indications for Use:

This Monarch® III C Cartridge IOL insertion device is indicated to fold/hold and insert Alcon IOLs that have the use of this inserter in their approved labeling.

4. Brief Summary of Nonclinical Test and Results:

The Monarch® III C Cartridge, in conjunction with the currently marketed Monarch® III handpiece, has been tested and found to deliver the AcrySof® Intraocular Lens in conformance with the requirements set forth in ISO 11979-3, ISO 10993, ISO 11135, and ISO 14971.

5. Comparison of Technological Characteristics to Predicate Device:

Device Name	Proposed Monarch® III IOL Delivery System (C Cartridge)	Monarch® II IOL Delivery System (C Cartridge)	Monarch® III IOL Delivery System (D Cartridge)
510(k) Number	**K112977**	**K003768**	**K063155**
Substantial Equivalence Characteristics			
Intended Use	Folding and injection of AcrySof® intraocular lenses into the posterior chamber of the eye	Folding and injection of AcrySof® intraocular lenses into the posterior chamber of the eye	Folding and injection of AcrySof® intraocular lenses into the posterior chamber of the eye
Anatomical Site of Use	Posterior chamber of the eye	Posterior chamber of the eye	Posterior chamber of the eye
Components	Identical reusable handpiece and single-use, sterile coated cartridge	Identical reusable handpiece and single-use, sterile coated cartridge	Reusable handpiece and single-use, sterile coated cartridge

Device Name	Proposed Monarch® III IOL Delivery System (C Cartridge)	Monarch® II IOL Delivery System (C Cartridge)	Monarch® III IOL Delivery System (D Cartridge)
510(k) Number	**K112977**	**K003768**	**K063155**
Substantial Equivalence Characteristics			
Handpiece (Identical)			
Material	Titanium alloy	Titanium alloy	Titanium alloy
Lens Injecting Mechanism	Push and turn	Push and turn	Push and turn
Configuration	Barrel and plunger assembly, the barrel has a chamber to accept the cartridge and the plunger advances the lens for injection	Barrel and plunger assembly, the barrel has a chamber to accept the cartridge and the plunger advances the lens for injection	Barrel and plunger assembly, the barrel has a chamber to accept the cartridge and the plunger advances the lens for injection
Sterilization	Flash autoclave or steam sterilization by user	Flash autoclave or steam sterilization by user	Flash autoclave or steam sterilization by user
Cartridge			
Material	Polypropylene with a polyvinylpyrolidione (PVP) coating on the inner lumen	Polypropylene with a polyvinylpyrolidione (PVP) coating on the inner lumen	Polypropylene with a polyvinylpyrolidione (PVP) coating on the inner lumen
Lens Folding Mechanism	Internal cartridge geometry	Internal cartridge geometry	Internal cartridge geometry
Nozzle	Tapered lumen	Tapered lumen	Tapered lumen
Configuration	Lens loading and folding area connected to a lens injecting nozzle	Lens loading and folding area connected to a lens injecting nozzle	Lens loading and folding area connected to a lens injecting nozzle
Sterilization	EtO	EtO	EtO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Catherine Goble
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Fort Worth, TX 76134

MAR 27 2012

Re: K112977
Trade/Device Name: Monarch® III IOL Delivery System (C Cartridge)
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I, Reserved
Product Code: MSS
Dated: March 6, 2012
Received: March 7, 2012

Dear Ms. Goble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112977

Device Name: Monarch III IOL Delivery System (C Cartridge)

Indications for Use:

This Monarch® III C Cartridge IOL insertion device is indicated to fold/hold and insert Alcon IOLs that have the use of this inserter in their approved labeling.

Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jennifer M. Brown

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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